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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/937,162

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Yoshihiro Sowa

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EXAMINER

GODDARD, LAURA B

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 10/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/937,162

Applicant(s)

SOWA ET AL.

Examiner

Laura B. Goddard, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 July 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6-20 and 25-29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 6-10, 14-17, 27 and 28 is/are allowed.
- 6) ☐ Claim(s) 18-20, 25, 26 and 29 is/are rejected.
- 7) ☒ Claim(s) 6 and 11-13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7/24/06</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The Amendment filed July 24, 2006 in response to the Office Action of January 25, 2006, is acknowledged and has been entered. Previously pending claim 6 has been amended. New claims 25-29 were added.

Upon further review and reconsideration, Groups 2-17 have been rejoined with Group 1 for examination (claims 6-20, new claims 26-29). Groups 18-32 have been rejoined into one Group drawn to an anticancer agent comprising a compound that increases the transcriptional activity mediated by Sp3 and a pharmaceutical carrier, wherein the anticancer agent is not TSA, trapoxin, or sodium butyrate (claims 21-24).

Claims 6-20 and 25-29 are currently under prosecution.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Objections

3. Claims 11-13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 11-13 recite "wherein the fusion protein comprises at least one glutamine-rich region of Sp3", however, these claims are all ultimately dependent on claim 6 which was amended to

Art Unit: 1642

recite " comprising at least one glutamine rich region of a TSA responsive domain of Sp3". Claims 11-13 fail to further limit claim 6.

4. Claim 6 is objected to because of the following informalities: It appears that the letter "Z" should be capitalized in the word "Zinc" when describing the Zinc finger to be consistent with the specification and claim 29. Appropriate correction is required.

NEW REJECTION

(based on new considerations)

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 18-20, 25, and 26 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps for evaluating the selected test agent for cellular anti-proliferation activity or the step of how to identify the selected test agent as having potential cellular anti-proliferative activity, and a correlation step describing how the results of the evaluation or identification assay relate back to the preamble of the method objectives.

NEW REJECTIONS

(necessitated by amendment)

Claim Rejections - 35 USC § 112

6. Claim 29 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 29 recites "the method of claim 6, wherein the fusion protein lacks at least part of a Zinc Finger region selected from the group consisting of amino acids... of human Sp3", however, independent claim 6 recites "lacking at least part of the zinc finger region of Sp3". It is unclear based on the two claims if there is one zinc finger region in Sp3 or if there is more than one. Do the three amino acid regions identified in claim 29 constitute *the* zinc finger region or are they separate zinc finger regions? Are there other zinc finger regions besides the three amino acid regions identified? Clarification is required.

7. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 26 recites the term "**potential cellular anti-proliferative activity**". This renders the claim indefinite because it is unclear **what** "**potential cellular anti-proliferative activity**" is relative to cellular anti-proliferative activity. The term "potential cellular anti-proliferative activity" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and

Art Unit: 1642

one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Dictionary-MSN Encarta teaches the definition of the adjective "potential" is "possible but as yet not actual: having a latent possibility or likelihood of occurring, or doing or becoming something" or "expressing possibility" (p. 1). This definition makes it unclear if the test agent selected from the method of claim 6 has a latent possibility or likelihood of developing cellular anti-proliferative activity or already has said activity but only exhibits it under certain circumstances, or may have said activity but it is unknown until further method steps are executed to determine the presence of said activity. Given the above reasons, the metes and bounds of the claim cannot be determined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claim 26 is rejected under 35 USC 112, first paragraph, as the specification does not contain a written description of the claimed invention. The limitation "identifying the selected test agent as having **potential cellular anti-proliferative activity**" has no clear support in the specification and the claims as originally filed. THIS IS A NEW MATTER REJECTION.

Applicant points to page 7, lines 5-20; page 10, lines 8-17 and page 26-30. However, a review of page 7, lines 5-20 reveals support for the structure requirements of functional Sp3 fragments of the fusion protein.

A review of page 10, lines 8-17 reveals support for identifying a test agent with increased reporter activity compared to a control as a candidate for a compound that inhibits proliferation of a tumor. Identifying the test agent as a candidate for a compound that inhibits proliferation of a tumor does not support the test agent already having potential cellular anti-proliferation activity. A review of p. 10 lines 8-17 also reveals support for "it was shown that transcriptional activity mediated by Sp3 was promoted in the signal transduction from TSA involved in the tumor-suppressing effect. This fact shows that a compound that can enhance the transcriptional activity mediated by Sp3 could have a tumor suppressing effect." While the specification supports TSA is involved in tumor-suppressing effects and TSA was involved in signal transduction promoting transcriptional activity mediated by Sp3, and while the specification extrapolates this example to show "that a compound that can enhance transcriptional activity mediated by Sp3 could have a tumor-suppressing effect", the cited support does not provide support for selecting a test agent that activates TSA responsive Sp3-mediated transcription and identifying the test agent as having potential cellular anti-proliferation activity.

A review of page 10, lines 26-30 reveal support for a compound which enhances the transcriptional activity mediated by Sp3 is thought to be applicable to a wide range of tumors. The potential cellular anti-proliferative activity of the claimed agent is not supported by this cited passage.

The cited support has been considered but has not been found persuasive because the cited support is not drawn to the identification of an agent that activates

Art Unit: 1642

TSA-responsive Sp3-mediated transcription and identifying that agent as **having potential cellular anti-proliferative activity.**

Rejections Withdrawn

9. The rejections of claims 6-17 under 35 USC 112, first paragraph, written description and scope of enablement (see sections #2 – 4 of the previous Office Action mailed January 25, 2006) have been withdrawn in view of the amendments.

10. **Conclusion:** Claims 6-10, 14-17, 27 and 28 appear to be allowable. Claims 6 and 11-13 are objected to. Claims 18-20, 25, 26, and 29 are rejected under 35 U.S.C. 112, second paragraph. Claim 26 is rejected under 35 USC 112, first paragraph.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura B. Goddard, Ph.D. whose telephone number is (571) 272-8788. The examiner can normally be reached on 8:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura B Goddard, Ph.D.
Examiner
Art Unit 1642


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER